

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Reconstitute as directed in the labeling. Dissolve an accurately measured representative volume of the sample in sufficient absolute methyl alcohol to give a solution of convenient concentration. Immediately further dilute an aliquot with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to the reference concentration of 1.0 unit of penicillin V (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, preparing the sample as follows: Reconstitute as directed in the labeling. Dissolve an accurately measured representative portion of the sample in absolute methyl alcohol and dilute with 1.0 percent potassium phosphate buffer, pH 6.0 (solution 1) to the prescribed concentration.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, using the sample reconstituted as directed in the labeling.

[42 FR 59863, Nov. 22, 1977, as amended at 50 FR 19919, May 13, 1985]

§ 440.171c Penicillin V tablets.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Penicillin V tablets are composed of penicillin V with or without one or more suitable and harmless diluents, binders, lubricants, and colorings. Each tablet contains 125 milligrams (200,000 units), 300 milligrams (500,000 units), or 500 milligrams (800,000 units) of penicillin V. Its potency is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams or units of penicillin V that it is represented to contain. Its moisture content is not more than 3 percent. It shall disintegrate within 1 hour. The penicillin V used conforms to the standards prescribed by § 440.71(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The penicillin V used in making the batch for potency, moisture, pH, penicillin V content, and crystallinity.

(b) The batch for potency, moisture, and disintegration time.

(ii) *Samples required:*

(a) The penicillin V used in making the batch: 10 packages, each containing approximately 300 milligrams.

(b) The batch: A minimum of 36 tablets.

(b) *Tests and methods of assay—(1) Potency—(i) Sample preparation.* Place a representative number of tablets into a high-speed glass blender jar containing sufficient absolute methyl alcohol to give a stock solution of convenient concentration. Blend for 2 to 5 minutes.

(ii) *Assay procedures.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(a) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter. Immediately dilute an aliquot of the methyl alcohol solution with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to the reference concentration of 1.0 unit of penicillin V per milliliter (estimated).

(b) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the methyl alcohol solution with solution 1 to the prescribed concentration.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *Disintegration time.* Proceed as directed in § 436.212 of this chapter.

[42 FR 59864, Nov. 22, 1977, as amended at 50 FR 19919, May 13, 1985]

§ 440.173 Penicillin V potassium oral dosage forms.

§ 440.173a Penicillin V potassium capsules.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Penicillin V potassium capsules are composed of penicillin V potassium and one or more suitable lubricants and fillers. Each capsule contains penicillin V potassium equivalent to 250 milligrams (400,000 units) or 500 milligrams (800,000 units) of penicillin V. The potency is satisfactory if it is not less than 90 percent and more than 115

percent of the number of milligrams or units of penicillin V that it is represented to contain. Its loss on drying is not more than 2.0 percent. The penicillin V potassium used conforms to the standards prescribed by § 440.73(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The penicillin V potassium used in making the batch for potency, loss on drying, pH, crystallinity, penicillin V content.

(b) The batch for potency and loss on drying.

(ii) Samples required:

(a) The penicillin V potassium used in making the batch: 10 packages, each containing approximately 300 milligrams.

(b) The batch: A minimum of 30 capsules.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Place a representative number of capsules into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes.

(ii) *Assay procedures.* Using the penicillin V working standard as the standard of comparison, assay by either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(a) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 1 to the reference concentration of 1.0 unit of penicillin V per milliliter (estimated).

(b) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(2) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

[42 FR 59864, Nov. 22, 1977, as amended at 50 FR 19919, May 13, 1985]

§ 440.173b Penicillin V potassium chewable tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Penicillin V potassium chewable tablets are composed of penicillin V potassium with suitable diluents, binders, buffers, colorings, and flavorings. Each tablet contains penicillin V potassium equivalent to 125 milligrams (200,000 units) or 250 milligrams (400,000 units) of penicillin V. Its potency is satisfactory if it contains not less than 90 percent and not more than 125 percent of the number of milligrams or units of penicillin V that it is represented to contain. The loss on drying is not more than 1.5 percent. The penicillin V potassium used conforms to the standards prescribed by § 440.73(a)(1).

(2) *Labeling.* In addition to the labeling requirements prescribed by § 432.5 of this chapter, this drug shall be labeled “penicillin V potassium tablets”.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The penicillin V potassium used in making the batch for potency, loss on drying, pH, penicillin V content, and crystallinity.

(b) The batch for potency and loss on drying.

(ii) Samples required:

(a) The penicillin V potassium used in making the batch: 10 packages, each containing approximately 300 milligrams.

(b) The batch: A minimum of 30 tablets.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Place a representative number of tablets into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes.

(ii) *Assay procedures.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(a) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 1 to the